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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yasuhide Kusaka

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1795

MAIL DATE

DELIVERY MODE

03/12/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/532,789	Applicant(s) KUSAKA ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/22/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of December 10, 2008 does not render the application allowable.

Claim Rejections - 35 USC § 112

2. Claims 1 and 3-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 1 requires the stepped portion to be greater in height with respect to the substrate than the reagent portion. Applicants have cited various passages in the specification and Figures 2 and 4 as support for this new limitation. There is no explicit teaching or suggestion in the text for this limitation. Figure 2 appears to show the top surface of the stepped portion (19) slightly higher than the top surface of the reagent portion (18). However, this appears to be purely accidental. The difference in height is so slight that the thicknesses of the stepped

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portion and the reagent portion appear to be arbitrary. As stated in the MPEP, “Proportions of features in a drawing are not evidence of actual proportions when drawings are not to scale.” See MPEP 2125.

3. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 3, 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 02/05776 A1. Because WO 02/05776 A1 is in Japanese all references will instead be made to US 7,267,750 B2 (“Watanabe”), which is an English language equivalent. US 7,267,750 B2 is a patent issued from a U.S. national stage application of WO 02/05776 A1. As such US 7,267,750 B2 is presumed to be a faithful translation of WO 02/05776 A1. MPEP 1893.01(d).

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Addressing claim 1, Watanabe discloses an analytical tool comprising a substrate (2), a capillary (17 – col. 05:46-48) formed on the substrate (Figure 2) and including an introduction port (11) for taking a sample liquid into the capillary (Figure 2); a stepped portion (15) projecting from the substrate for preventing the sample liquid in the capillary from moving further (inherent property - see Figure 2. The stepped portion is clearly an obstacle to further sample flow); and a reagent portion (8) provided in the capillary between the introduction port and the stepped portion (Figure 2);

wherein the stepped portion is greater in height with respect to the substrate than the reagent portion (Figure 2).

Addressing claim 3, the stepped portion comprises electrically insulating layer 15 on conductive layer 6. See Figure 2; col. 04:07-13; and col. 04:45-47.

Addressing claim 4, for the additional limitation of this claim see Figure 1 and col. 04:48-50. Note electrodes 3 and 4.

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6. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watanabe as applied to claims 1, 3, and 4 above, and further in view of Ikeda et al. US 5,582,697 ("Ikeda").

Addressing claim 5, In Watanabe the conductive layer is a measurement or counter electrode.

Ikeda discloses an analytical tool comprising a substrate (1), a capillary (11) formed on the substrate and including an introduction port (right end of Figure 1) for taking a sample liquid into the capillary and a conductive layer formed as a dummy electrode (7) which does not contribute to the voltage application to the sample liquid (col. 04:24-30). It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a dummy electrode as taught by Ikeda in the invention of Watanabe, which would also be under an insulating layer as are the counter and working electrode, because as taught by Ikeda then it could be determined whether the sample liquid has covered the entire reaction layer without affecting the measurement as would occur in a two-electrode system. See in Ikeda col. 10:58-65 and col. 02:17-30.

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Addressing claim 6, as a first matter whether the dummy electrode is formed simultaneously with the plurality of electrodes is a product-by-process that does not materially distinguish the claimed invention from that disclosed by Watanabe as modified by Ikeda. In any event, it would have been obvious to one with ordinary skill in the art at the time of the invention to form the dummy electrode simultaneously with the plurality electrodes because will lessen the number of manufacturing steps than if the electrodes are formed sequentially.

Addressing claim 7, In Watanabe the conductive layer is a measurement or counter electrode.

Ikeda discloses an analytical tool comprising a substrate (1), a capillary (11) formed on the substrate and including an introduction port (right end of Figure 1) for taking a sample liquid into the capillary and a conductive layer formed as a detection electrode (7) for detecting whether or not the sample liquid of an amount necessary for analysis is supplied into the capillary (col. 04:24-30). It would have been obvious to one with ordinary skill in the art at the time of the invention to provide a detection electrode as taught by Ikeda in the invention of Watanabe, which would also be under an insulating layer as are the counter and working electrode, because as taught by Ikeda then it could be determined whether the sample liquid has covered the entire reaction layer without affecting the measurement as would occur in a two-electrode system. See in Ikeda col. 10:58-65 and col. 02:17-30.

Addressing claim 8, for the claimed air vent note element 12 in Figure 2 in Watanabe; for the insulating layer being configured as claimed note how insulating layer 15 sits over the electrodes in Figure 1 in Watanabe; and for the claimed view in the thickness direction of the substrate see Figure 1 in Watanabe.

Final Rejection

7. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Nogueroles/
Primary Examiner, Art Unit 1795
March 11, 2009